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U.S. COURT OF FEDERAL CLAIMS

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1262V Filed: March 14, 2018 Not to be published FILED

MAR 1 4 2018

U.S. COURT OF FEDERAL CLAIMS

SALLY VOICE,

Petitioner,

V.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

<u>Sally Voice</u>, Princeton, IL, for petitioner (pro se). <u>Lisa A. Watts</u>, Washington, DC, for respondent.

Influenza ("flu") vaccine; chronic inflammatory demyelinating polyneuropathy ("CIDP"); failure to respond to order to show cause

MILLMAN, Special Master

DECISION1

On October 4, 2016, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10–34 (2012) (the "Vaccine Act"), alleging that influenza ("flu") vaccine administered on October 10, 2015 caused her chronic inflammatory idiopathic polyneuropathy ("CIDP"). Pet. Preamble, at 1-2, and at ¶¶ 3, 11.

Petitioner filed her statement, dated September 29, 2016, as Exhibit 1. She states that she was healthy prior to vaccination. Ex. 1, at \P 2. She dates the onset of her illness to Thanksgiving

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall redact such material from public access.

2015 when she did not have the energy to make Thanksgiving dinner. <u>Id.</u> at ¶ 4. In the weeks leading to Christmas, she writes she dragged herself to work and then, after returning home, crawled into bed. <u>Id.</u> She says she was so exhausted, her legs felt as if she had run up 10 flights of stairs. <u>Id.</u> at ¶ 5. In addition to fatigue, she writes she had pain in her legs, feet, and arms. <u>Id.</u> She says she began avoiding helping to transfer patients because she thought she might hurt them from weakness. <u>Id.</u> Because she was losing sensation in her hands, she writes she had trouble starting IVs. <u>Id.</u> She states that, in mid-December, she awoke with horrible, burning, cold, stabbing pain in her arms and legs, and fell to the floor because her legs would not support her. <u>Id.</u> at ¶ 6. After a couple of hours, this passed but it recurred two more times in the next few weeks. <u>Id.</u> None of the details petitioner describes in paragraphs 4-6 are included in the histories she gave to her doctors.

FACTS

Pre-vaccination records

Petitioner, a registered nurse at Banner Thunderbird in the neurology intensive care unit, was born on January 18, 1973. Med. recs. Ex. 7, at 5.

On July 31, 2013, petitioner saw a physical therapist. Med. recs. Ex. 9, at 1. The P-T assessed her with bipolar disorder and ADHD. Med. recs. Ex. 9, at 1.

On February 19, 2015, petitioner saw Dr. Kim Lucas, complaining of numbness and tingling in her left foot, and an abnormal CT scan. Med. recs. Ex. 5, at 2. Her left leg became numb two weeks earlier after she fell asleep with her knees bent on a hard chair. Id. The numbness had improved, but she had weakness in her left outer shin and some slap foot. Id. She was also getting cramps in her lower calf and the top of her foot with dorsiflexion. Id. In addition, petitioner had sleep problems. Id. She worked from 7:00 p.m. to 7:00 a.m. four days a week and could not fall asleep. Id. She could not shut off her head. Id. Petitioner also had attention deficit disorder and insulin-dependent diabetes mellitus. Id. She was five foot seven inches tall and weighed 184.7 pounds, giving her a BMI of 28.77. Id. Dr. Lucas thought petitioner's left leg numbness was due to compression from falling asleep in a hard chair. Id. at 3. Dr. Lucas attributed petitioner's insomnia to shift work. Id.

On April 29, 2015, petitioner saw Dr. Steven Kanner, a gastroenterologist, because of diarrhea for about two years. Med. recs. Ex. 5, at 52. In a review of systems, Dr. Kanner notes that petitioner complained of numbness or tingling in her hands when she woke in the morning. <u>Id.</u> at 53. She also complained of arthritis and back pain. <u>Id.</u> Dr. Kanner diagnosed petitioner with irritable bowel syndrome, diarrhea, some constipation, bloating, and cramps. <u>Id.</u> at 54.

On July 27, 2015, petitioner saw Dr. Abdullah Hanna Moussa, an endocrinologist, for her uncontrolled type 1 diabetes. Med. recs. Ex. 8, at 7. She has had diabetes since she was 23 years of age. <u>Id.</u> Dr. Moussa discussed the importance of controlling petitioner's blood sugar and the

need for diabetic foot care. <u>Id.</u> Petitioner had a dilated eye examination in March 2015, which showed an early stage of diabetic retinopathy. <u>Id.</u> She took ibuprofen daily for her back pain. <u>Id.</u> She has had low back pain since 1993 due to accidents. Med. recs. Ex. 12, at 30.

Post-vaccination records

On October 10, 2015, petitioner received flu vaccine. Med. recs. Ex. 2, at 1.

On October 29, 2015, petitioner saw Dr. Kim Lucas for ADD. Med. recs. Ex. 7, at 18. Dr. Lucas stopped her long-acting Ritalin extended release, and refilled a prescription for 20 mg-Ritalin tablets. Id.

On January 6, 2016, three months after petitioner received flu vaccine, petitioner saw Dr. Lucas, complaining of burning, stabbing pains in her hands and feet, which woke her up. <u>Id.</u> at 16. Initially her hands were worse. <u>Id.</u> She felt better if she got up and moved. <u>Id.</u> Dr. Kim's assessment was foot and hand pain and insomnia. <u>Id.</u> She recommended that petitioner see Dr. Darry Johnson, a neurologist, to have a nerve conduction study of both upper and lower extremities. Id. at 17.

On January 27, 2016, petitioner saw Dr. Lucas for a well woman examination. <u>Id.</u> at 14. Petitioner was alert, pleasant, and in no acute distress. <u>Id.</u>

On February 8, 2016, petitioner saw Dr. Darry Johnson, a neurologist. <u>Id.</u> at 11. Petitioner said that for the past month (since early January 2016, or three months post-vaccination), she had numbness in both arms with hot sensations in her fingers. <u>Id.</u> She felt better if she stretched her back and got out of bed, but weakness in her legs could occur. <u>Id.</u> She had numbness in her feet just once. <u>Id.</u> The numbness in her hands was intermittent. <u>Id.</u> She had a lot of tightness and pain in her upper spine. <u>Id.</u> On physical examination, petitioner's deep tendon reflexes were 2/4 at the biceps, triceps, brachioradialis, knees, and ankles. <u>Id.</u> at 12. She had 5/5 strength in all four limbs and normal tone. <u>Id.</u> Her sensory testing for position, vibration, temperature, pinprick, and light touch were intact and equal distally over her feet. <u>Id.</u> Her stride, length, and arm swing were normal. She turned without difficulty. <u>Id.</u> Dr. Johnson diagnosed petitioner with cervicalgia, low back pain, paresthesia, and hand numbness. <u>Id.</u>

On February 25, 2016, petitioner saw Dr. Lucas for pain in her foot and hand. <u>Id.</u> at 10. Also on that date, she saw Dr. Johnson for an EMG and nerve conduction study. <u>Id.</u> at 9.

On March 3, 2016, Dr. Johnson diagnosed petitioner with CIDP, carpal tunnel syndrome, and paresthesia. <u>Id.</u> at 7.

On April 14, 2016, petitioner saw Dr. Johnson. <u>Id.</u> at 5. He notes that, for the past month, petitioner had had numbness in both arms with hot sensations in her fingers. She was better if she stretched her back and got out of bed, but leg weakness could occur. She also had

foot numbness one time. Her hands were intermittently numb. Dr. Johnson was under the assumption that petitioner's CIDP was concomitant with her flu vaccination, although there is no indication in the medical records that petitioner informed Dr. Johnson that she received flu vaccine on October 10, 2015. Petitioner received IVIG every three weeks, which she felt made a difference. Dr. Johnson also suspected that petitioner had diabetic peripheral neuropathy and added that to the list of diagnoses. <u>Id.</u>

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" <u>i.e.</u>, "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Petitioner must show not only that but for the vaccine, she would not have CIDP, but also that the vaccine was a substantial factor in bringing about her CIDP. <u>Shyface v. Sec'y of HHS</u>, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Petitioner had pre-vaccination symptoms of left leg numbness in early February 2015, eight months before her flu vaccination, which she did not share with Dr. Darry Johnson, her neurologist, who thought the close proximity to her flu vaccination might indicate causality of her CIDP mixed in with symptoms of diabetic neuropathy. She complained of numbness or tingling to Dr. Kanner on April 29, 2015. If indeed petitioner's CIDP onset preceded her flu vaccination, petitioner will have to prove significant aggravation, which the Vaccine Act, 42 U.S.C. § 300aa-33(4) defines as: "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health."

The undersigned cannot rule in petitioner's favor based solely on her allegations "unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). The medical records do not substantiate petitioner's making any neurologic complaints post-flu vaccination until three months had elapsed. If indeed there is an interval of three months between flu vaccination and onset or significant aggravation of CIDP, the undersigned will find it difficult to rule in petitioner's favor as the undersigned has never gone beyond two months for a causal interval between vaccination and onset of demyelinating disease. See Corder v. Sec'y of HHS,

No. 08-228V, 2011 WL 2469736 (Fed. Cl. Spec. Mstr. May 31, 2011) (dismissed four-month onset case of GBS following flu vaccination; two months is the outer limit for causation).

Petitioner filed medical records on October 28, 2016, November 3, 2016, December 9, 2016, January 5, 2017, January 30, 2017, and March 27, 2017, and a Statement of Completion on April 12, 2017. On April 13, 2017, the undersigned issued an Order setting a deadline of June 12, 2017 for petitioner to file an expert report. On June 12, 2017, petitioner filed a motion for an extension of time until July 12, 2017 to file an expert report, which the undersigned granted. On July 12, 2017, petitioner's counsel filed a motion to withdraw, which the undersigned granted on the same date.

On September 21, 2017, the undersigned held a telephonic status conference with petitioner pro se and respondent's counsel. Petitioner stated she had contacted attorneys but had not found a representative yet.

On November 9, 2017, the undersigned held a telephonic status conference with petitioner pro se and respondent's counsel. Petitioner said she was still looking for counsel and was trying to get her physicians to amend their medical records under the HIPPA law. She had contacted her personal care physician Dr. Kim Lucas and her neurologist Dr. Darry Johnson. Petitioner filed nothing subsequent to this telephonic conference. On February 2, 2018, the undersigned issued an Order to Show Cause why this case shall not be dismissed, giving her until March 2, 2018 to file either a status report stating how her attempt to have Dr. Lucas and Dr. Johnson amend their medical records was proceeding, a motion to substitute counsel, or a motion to dismiss the petition. Petitioner filed nothing.

The undersigned now **DISMISSES** this case under Vaccine Rule 21(b)(1) based on both petitioner's failure to prosecute and her failure to obey the undersigned's Order to Show Cause. In addition, petitioner has failed to make a prima facie case of causation in fact.

CONCLUSION

The petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment herewith.²

IT IS SO ORDERED.

Dated: March 14, 2018

Laura D. Millman Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.